

TENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

KIDDLE, Simon
Mewburn Ellis
York House
23 Kingsway
London WC2B 6HP
ROYAUME-UNI

Date of mailing (day/month/year) 24 April 2001 (24.04.01)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference SJK/BP5864368	
International application No. PCT/GB00/03054	International filing date (day/month/year) 08 August 2000 (08.08.00)

1. The following indications appeared on record concerning: <input checked="" type="checkbox"/> the applicant <input type="checkbox"/> the inventor <input type="checkbox"/> the agent <input type="checkbox"/> the common representative		
Name and Address THE VICTORIA UNIVERSITY OF MANCHESTER Oxford Road Manchester M13 9PL United Kingdom	State of Nationality GB	State of Residence GB
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning: <input checked="" type="checkbox"/> the person <input type="checkbox"/> the name <input type="checkbox"/> the address <input type="checkbox"/> the nationality <input type="checkbox"/> the residence		
Name and Address INTERNATIONAL INTERSTITIAL TECHNOLOGIES LIMITED 21 Southampton Row London WC1B 5HS United Kingdom	State of Nationality GB	State of Residence GB
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	
3. Further observations, if necessary:		
4. A copy of this notification has been sent to: <input checked="" type="checkbox"/> the receiving Office <input checked="" type="checkbox"/> the designated Offices concerned <input type="checkbox"/> the International Searching Authority <input type="checkbox"/> the elected Offices concerned <input type="checkbox"/> the International Preliminary Examining Authority <input type="checkbox"/> other:		

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer R. Raissi Telephone No.: (41-22) 338.83.38
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NT COOPERATION TREAT

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

KIDDLE, Simon
Mewburn Ellis
York House
23 Kingsway
London WC2B 6HP
ROYAUME-UNI

Date of mailing (day/month/year) 24 April 2001 (24.04.01)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference SJK/BP5864368	
International application No. PCT/GB00/03054	International filing date (day/month/year) 08 August 2000 (08.08.00)

1. The following indications appeared on record concerning:		
<input type="checkbox"/> the applicant	<input type="checkbox"/> the inventor	<input checked="" type="checkbox"/> the agent
<input type="checkbox"/> the common representative		
Name and Address TUNNICLIFFE, Peter, Barry Chester Court Church Close Broadway Worcestershire WR12 7AH United Kingdom	State of Nationality	State of Residence
	Telephone No. 01386 858 127	
	Facsimile No. 01386 858 127	
	Teleprinter No.	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:		
<input checked="" type="checkbox"/> the person	<input type="checkbox"/> the name	<input type="checkbox"/> the address
<input type="checkbox"/> the nationality	<input type="checkbox"/> the residence	
Name and Address KIDDLE, Simon Mewburn Ellis York House 23 Kingsway London WC2B 6HP United Kingdom	State of Nationality	State of Residence
	Telephone No. 020 7240 4405	
	Facsimile No. 020 7240 9339	
	Teleprinter No.	
3. Further observations, if necessary:		
4. A copy of this notification has been sent to:		
<input checked="" type="checkbox"/> the receiving Office	<input checked="" type="checkbox"/> the designated Offices concerned	
<input type="checkbox"/> the International Searching Authority	<input type="checkbox"/> the elected Offices concerned	
<input type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:	

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer R. Raissi
	Telephone No.: (41-22) 338.83.38

PCT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE
 in its capacity as elected Office

Date of mailing (day/month/year) 29 May 2001 (29.05.01)	
International application No. PCT/GB00/03054	Applicant's or agent's file reference SJK/BP5864368
International filing date (day/month/year) 08 August 2000 (08.08.00)	Priority date (day/month/year) 11 August 1999 (11.08.99)
Applicant VADGAMA, Pankaj, Madganal	

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

07 March 2001 (07.03.01)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Pascal Piriou Telephone No.: (41-22) 338.83.38
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TENT COOPERATION TREA

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

KIDDLE, Simon
Mewburn Ellis
York House
23 Kingsway
London WC2B 6HP
ROYAUME-UNI

Date of mailing (day/month/year) 05 July 2001 (05.07.01)	IMPORTANT NOTIFICATION
Applicant's or agent's file reference SJK/BP5864368	
International application No. PCT/GB00/03054	International filing date (day/month/year) 08 August 2000 (08.08.00)

1. The following indications appeared on record concerning:

☒ the applicant

 ☐ the inventor

 ☐ the agent

 ☐ the common representative

Name and Address INTERNATIONAL INTERSTITIAL TECHNOLOGIES LIMITED 21 Southampton Row London WC1B 5HS United Kingdom	State of Nationality GB	State of Residence GB
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person

 ☒ the name

 ☐ the address

 ☐ the nationality

 ☐ the residence

Name and Address IIT LIMITED 21 Southampton Row London WC1B 5HS United Kingdom	State of Nationality GB	State of Residence GB
	Telephone No.	
	Facsimile No.	
	Teleprinter No.	

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

<input checked="" type="checkbox"/> the receiving Office	<input type="checkbox"/> the designated Offices concerned
<input type="checkbox"/> the International Searching Authority	<input checked="" type="checkbox"/> the elected Offices concerned
<input checked="" type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer S. Buttay Telephone No.: (41-22) 338.83.38
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P. 444.	FOR FURTHER ACTION <small>see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.</small>	
International application No. PCT/GB 00/ 03054	International filing date (day/month/year) 08/08/2000	(Earliest) Priority Date (day/month/year) 11/08/1999
Applicant THE VICTORIA UNIVERSITY OF MANCHESTER		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of Invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

2

☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

GB 00/03054

A. CLASSIFICATION OF SUBJECT MATTER
 IPC 7 G01N27/327 A61B5/00 C12Q1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B C12Q G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

BIOSIS, COMPENDEX, INSPEC, EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 58250 A (ELAN CORP PLC) 23 December 1998 (1998-12-23) page 19, line 5 figures 2,3 ---	1-9, 11-27
X	WO 96 14026 A (KELLY JOHN GERARD ;ELAN MED TECH (IE); GROSS JOSEPH (IE)) 17 May 1996 (1996-05-17) page 39, line 17 -page 40, line 2 figures 16,17 ---	1-13, 15-27
X	US 5 660 163 A (LUCISANO JOSEPH Y ET AL) 26 August 1997 (1997-08-26) abstract column 5, line 55 - line 59 column 9, line 32 - line 39 figure 4 --- -/--	1-9, 11-17, 20-27



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

3 November 2000

Date of mailing of the international search report

09/11/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Muñoz, M

INTERNATIONAL SEARCH REPORT

International Application No

GB 00/03054

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 264 210 A (CANPOLAR INC) 20 April 1988 (1988-04-20) column 3, line 22 - line 43 column 4, line 9 - line 30 column 5, line 49 -column 7, line 5 figures 1,4,5 ---	1-19,21, 22,25-27
A	WO 96 06947 A (HELLER ADAM ;PISHKO MICHAEL V (US)) 7 March 1996 (1996-03-07) figure 1 page 4, line 28 -page 5, line 24 claims 1,2,5,12,13,20,24-28 -----	1-27

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

GB 00/03054

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9858250	A	23-12-1998	IE 970443 A	16-12-1998
			AU 8031898 A	04-01-1999
			EP 0990151 A	05-04-2000
			ZA 9805189 A	08-01-1999
<hr/>				
WO 9614026	A	17-05-1996	IE 940865 A	15-05-1996
			AU 693279 B	25-06-1998
			AU 3880095 A	31-05-1996
			AU 713246 B	25-11-1999
			AU 6370298 A	12-11-1998
			CA 2204370 A	17-05-1996
			EP 0789540 A	20-08-1997
			JP 10508518 T	25-08-1998
			NZ 295458 A	29-04-1999
			ZA 9509309 A	29-05-1996
<hr/>				
US 5660163	A	26-08-1997	US 5497772 A	12-03-1996
			US 5791344 A	11-08-1998
<hr/>				
EP 0264210	A	20-04-1988	CA 1291209 A	22-10-1991
			JP 63109365 A	14-05-1988
<hr/>				
WO 9606947	A	07-03-1996	US 5593852 A	14-01-1997
			AU 3501695 A	22-03-1996
			EP 0778897 A	18-06-1997
			JP 10505421 T	26-05-1998
			US 5965380 A	12-10-1999
			US 6083710 A	04-07-2000
			US 6121009 A	19-09-2000
<hr/>				

REPLACED BY
PCT 34 AND 1

WHAT WE CLAIM IS:-

1. A sensor device comprising an enzyme electrode sensor,
characterised in that the enzyme is retained within one or
5 more cavities formed in the said electrode sensor.
2. A sensor device as claimed in Claim 1 wherein the cavity
or cavities are placed along the length of the electrode
core, so that the enzyme therein can face laterally
instead of being on a mechanically vulnerable tip,
10 especially a wire tip.
3. A sensor device as claimed in Claim 1 or Claim 2 wherein
the core of active electrode material is made of a noble
metal, for example gold or platinum, or an alloy of these
with each other or one or more other elements, and
15 preferably of platinum itself or platinum hardened by
alloying, e.g. with a proportion of iridium.
4. A sensor device as claimed in any of Claims 1 to 3
wherein the shape of the sensor device is of a
substantially circular cross-section, for example as is
20 customary when the active electrode material is a wire
core, e.g. conventional drawn metal wire as available
commercially,
5. A sensor device as claimed in any of Claims 1 to 4
wherein the size of the core material is in the range 50
25 to 150 μm .
6. A sensor device as claimed in any of Claims 1 to 5
wherein the core of active electrode material is covered
with a coating of insulating material to prevent bare
active electrode material coming into contact with the
30 environment media and the analyte to be detected and
measured.
7. A sensor device as claimed in any of Claims 1 to 6
wherein the cavity or cavities required are made by
removing part of the insulation to expose a bare core of
35 active electrode material and the cavity (or cavities)

form in the insulation layer and then the enzyme can then be placed therein.

8. A sensor device as claimed in any of Claims 1 to 7 wherein the cavity or cavities required are made by removing both the insulation and some of the core of active electrode material can be removed by using an appropriate micro-machining technique, so that the cavity (or cavities) form in the core of active electrode material itself.
9. A sensor device as claimed in any of Claims 1 to 8 wherein the one or more cavity is in the form of a slot cut into the sensor in a substantially lengthways direction (i.e. in the direction of the axis of a wire electrode),
10. A sensor device as claimed in any of Claims 1 to 9 wherein one or more cavity passes completely through the core of electrode material, in effect forming a tunnel, open at both ends, running transversely to the general direction of the inner core, so allowing enzyme to be packed into this tunnel and to be exposed to analyte-containing media at both ends of the cavity (tunnel).
11. A sensor device as claimed in any of Claims 1 to 10 wherein the cavity or cavities required are made by mechanical procedures, for example drilling, punching, grinding, boring, cutting, or any combination of these techniques,
12. A sensor device as claimed in any of Claims 1 to 11 wherein the cavity or cavities required are made by an ion beam or laser method (commonly referred to a "micro-machining").
13. A sensor device as claimed in any of Claims 1 to 12 wherein the size of the cavity (or cavities) is up to about half of the overall thickness of the sensor material, so that the strength of the sensor is not unduly reduced.

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14. A sensor device as claimed in any of Claims 1 to 13 wherein there are multiple cavities of substantially the same shape and size.
- 5 15. A sensor device as claimed in any of Claims 1 to 14 wherein the cavity form can readily retain the enzyme, preferably like "pits," which can achieve a stronger hold on their enzyme contents.
- 10 16. A sensor device as claimed in any of Claims 1 to 15 wherein the cavity (or cavities) contain more than one enzyme, e.g. as laminate layers, so that a succession of reactions can be catalysed --- one enzyme acting on an analyte substrate to form a product which, in turn, is acted upon by the second enzyme to generate a further product which can then be satisfactorily detected and
- 15 measured at the active electrode surface.
17. A sensor device as claimed in any of Claims 1 to 16 wherein the enzyme is fixed in place in the cavity (or cavities) by cross-linking, e.g. by treatment with glutaraldehyde.
- 20 18. A sensor device as claimed in any of Claims 1 to 17 having a coating over the enzyme held within the (or cavities) formed by depositing layers of material over it after enzyme has been put into the cavities
- 25 19. A sensor device as claimed in Claim 18 wherein the over-coating layer is composed of material of appropriate permeability (simple or selective) to regulate the passage of components from a sample under examination to the enzyme and active electrode surface, or excluding or limiting access by materials which could interfere with
- 30 the measurements.
20. A sensor device as claimed in any of Claims 1 to 19 wherein the enzyme is and oxidase or dehydrogenase enzyme, for example glucose oxidase.
- 35 21. A sensor device having one or more enzyme-containing cavities, substantially as described.

- 17 -

22. Use of a sensor device as claimed in any of Claims 1 to 21 for the purpose of determining or monitoring an analyte.
23. Use of a sensor device, as claimed in Claim 22, wherein
5 the analyte is glucose.
24. Use of a sensor device, as claimed in Claim 22 or Claim 23, in a biological environment or with biological media.
25. Method for analysis using a sensor device as claimed in
10 any of Claims 1 to 21, especially electrolytic analysis and preferably using an amperometric procedure with the active electrode material as the anode.
26. Method as claimed in Claim 25 wherein the analysis is carried out in vivo, for example with the sensor device being inserted into the site for making measurements
15 directly (transcutaneously into tissue) or through a cannula or fine tubing, e.g. of nylon.
27. Method for analysis using an enzyme-containing sensor device substantially as described.

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REC'D 12 NOV 2001

WIPO

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SJK/BP5864368		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB00/03054	International filing date (day/month/year) 08/08/2000	Priority date (day/month/year) 11/08/1999
International Patent Classification (IPC) or national classification and IPC G01N27/327		
Applicant IIT LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 07/03/2001	Date of completion of this report 08.11.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Komenda, P Telephone No. +49 89 2399 2777 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/03054

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-13 as originally filed

Claims, No.:

1-22 as received on 25/10/2001 with letter of 23/10/2001

Drawings, sheets:

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/03054

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	6,9,10,16-18,22
	No:	Claims	1-5,7,8,11-15,19-21
Inventive step (IS)	Yes:	Claims	
	No:	Claims	6,9,10,16-18,22
Industrial applicability (IA)	Yes:	Claims	1-22
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Section V:

Reference is made to the following documents:

D1 = WO 98/58250

D2 = WO 96/06947

N: The subject-matter as presently defined in independent claim 1 is anticipated by document D1 which reveals a sensor device comprising an electrode carrying an enzyme, the electrode having a plurality of cavities formed along the length of the electrode which retain the enzyme (see figure 3 and related text). Claim 1 defines the electrode to be a "wire" electrode whereas according to D1 the electrode is a "needle" electrode. At first it should be mentioned that the term "wire" electrode does not restrict the electrode to a particular diameter. D2 for example, which was acknowledged by the applicant to disclose a "wire" electrode, defines the outer diameter of the wire to be "about 0.25 mm or less" (page 8, line 2). The needle in D1 has a diameter of 0.3 mm (page 20, line 7) which thus, in view of the dimensions given in D2, is comparable to a "wire" electrode. It is thus considered, that for the purpose of assessing novelty, the term "wire" electrode cannot be distinguished from the term "needle" electrode and that consequently, claim 1 lacks novelty over D1 (Article 33(2) PCT).

The features of dependent claims 2-5, 7, 8, 11-15 and 19-21 are also known from D1 and thus add nothing new to the claims to which said dependent claims refer.

IS: With respect to claim 6:

As far as can be understood, the problem to be solved by the present application is to avoid the mechanical loss of enzyme related to conventional type of electrodes during insertion into tissue. This problem has already been solved in the art by D1 which proposes to provide a plurality of cavities along the length of the electrodes which retain the enzyme. The subject-matter of claim 6 can thus be considered an alternative to the device of D1. It appears, however, obvious for the skilled man to further reduce the "size" of the needle when circumstances make it desirable e.g. when patient discomfort shall be reduce. A subject-matter of claim 6 is thus considered obvious in the light of D1 (Article 33(3) PCT).

Similar considerations apply to the features of claims 9, 10, 16-18 and 22 relating to the immobilisation of the enzyme by cross-linking, the production of the cavities and the use of the electrode - features which appear to be well known to the skilled person (Article 33(3) PCT).

IA: Industrial applicability is acknowledged (Article 33(4) PCT).

Section VII:

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor is this document identified therein. Moreover, a document reflecting the prior art described on pages 2 and 3, is not identified in the description.
2. The description is not in conformity with the new claims, see in particular figures 1 and 4.
3. The features of the device claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Section VIII:

1. Claims 11, 16 and 18 relate to the method of using/making the sensor but do not limit the device in terms of technical features thereof.

Claims:

1. A sensor device comprising a wire electrode sensor carrying an enzyme, the wire electrode having a plurality of cavities formed along the length of the electrode
5 which retain the enzyme.

2. The sensor device of claim 1, wherein the cavities are circular, oval, square, polygonal, cruciform, star-shaped or combinations thereof.

10

3. The sensor device of claim 1 or claim 2, wherein the wire electrode sensor is formed from a noble metal.

4. The sensor device of claim 3, wherein the noble
15 metal is gold, platinum, or an alloy thereof.

5. The sensor device of claim 4, wherein the alloy is platinum-iridium.

20 6. The sensor device of any one of the preceding claims, wherein the wire has an outer diameter of 50 to 150µm.

7. The sensor device of any one of the preceding
25 claims, wherein the enzyme is an oxidase or dehydrogenase enzyme.

8. The sensor device of claim 7, wherein the enzyme is glucose oxidase.

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9. The sensor device of any one of the preceding claims, wherein the enzyme is retained in the cavities by cross-linking.

10. The sensor device of claim 9, wherein the enzyme is cross-linked using glutaraldehyde.

11. The sensor device of claim 10, wherein the sensor device is used for the measurement of glucose concentrations in tissues.

12. The sensor device of any one of the preceding claims, wherein the electrode further comprises a coating over the electrode and enzyme present in the cavities.

13. The sensor device of claim 12, wherein the coating regulates the passage of components from a sample under examination to the enzyme and active electrode surface.

14. The sensor device of claim 13, wherein the coating is a polymer or polymer composition.

15. The sensor device of claim 14, wherein the polymer composition is a polyaryl ether sulphone or a modified polyurethane.

16. The sensor device of any one of the preceding claims, wherein the cavities are produced by micromachining with an ion beam or a laser.

17. The sensor device of any one of the preceding claims, wherein the surface or the wire electrode is covered by a coating of insulating material.

18. The sensor device of claim 17, wherein the cavities are produced by removing insulating material from the electrode.

19. Use of a sensor device of any one of the preceding claims for determining or monitoring an analyte.
20. The use of claim 19, wherein the analyte is glucose.
- 5 21. The use of claim 19 or claim 20, wherein the analyte is determined or monitored in an amperometric procedure.
- 10 22. The use of any one of claims 19 to 21, wherein analyte is determined or monitored by inserting the electrode transcutaneously through cannula.